

REMARKS

The present application relates to hybrid maize plant and seed 32H58. Claims 9-11, 13-19, 22-24, 26-32, 34-40 have been canceled. Claims 43-60 have been added. Claims 5, 8, 12, 21, 25, 33, and 42 have been amended. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

Detailed Action

A. Status of the Application

Applicant acknowledges the indefiniteness rejection and the art rejection of record of claims 10, 14, 18, 23, 27 and 31 as overcome.

B. Specification

Applicant submits the Deposit section on page 42 has been amended in order to properly include both the hybrid maize plant 32H58 and the inbred parents GE535764 and GE500871 within the Deposit paragraph. The changes do not add new matter as there is literal support for the minor changes on pages 7 in the originally filed specification. The specification has now been amended to correct these minor changes.

In addition, Applicant respectfully submits that the actual ATCC deposit of the hybrid maize plant and the two inbred plants will be delayed until the receipt of notice that the application is otherwise in condition for allowance, in compliance under 37 C.F.R. §§ 1.801-1.809. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination and the name and address of the depository. The claims will also be amended to recite the ATCC deposit number. Applicant submits that at least 2,500 seeds of hybrid maize plant 32H58 and the inbred parents GE535764 and GE500871 will be deposited with the ATCC. Applicant further asserts that the deposits will be made without restriction

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 8, 11-19, 21, 24-32, 39, and 42 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point and distinctly claim the subject

matter which Applicant regards as the invention, as stated in the last Office Action for claims 5-8, 10-19, 21, and 23-32

Applicant respectfully traverses this rejection. Applicant wishes to reiterate that it is well known in the art that the hybrid 32H58 will represent elite germplasm produced from the crossing of inbred parent lines GE535764 and GE500871 for character traits of major importance which will subsequently be used in a breeding population to further those elite traits. Applicant further asserts that it would be understood by one skilled in the art that the claimed maize plant or its parts contain at least 50% of the alleles inherited from the hybrid maize plant 32H58 having been deposited under ATCC Accession No. to be disclosed upon allowance of subject matter. In addition, "[W]hen not defined by Applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art", thereby alleviating this rejection. See *In re Sneed*, 710 F.2d 1544, 218 U.S.P.Q. 385 (Fed. Cir. 1983); See also MPEP § 2111.02. However, in order to expedite prosecution Applicant has canceled claims 9-11, 13-19, 22-24, 26-32, and 34-40, and additionally amended claims 8, 12, 21, 25, and 42, thereby alleviating this rejection to said claims.

The Examiner rejects claim 39 as indefinite for the recitation "32H58 maize plant ...deriving at least 50% of its alleles from 32H58" as confusing.

Applicant has now canceled claim 39, thus alleviating this rejection.

Claim 42 stands rejected as indefinite for failing to further limit claim 41.

Applicant has now amended claim 42 to be rewritten as follows: --A male sterile maize plant produced by the method of claim 41.--, as suggested by the Examiner, thereby alleviating this rejection. Applicant thanks the Examiner for the suggested language.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 11, 15, 19, 24, 28, 32, 34 and 38-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that there is

no literal basis in the specification for the 50% allelic derivation language. Further the Examiner states that there is no basis for the double haploid method.

Applicant respectfully traverse this rejection. However, in an effort to expedite prosecution, Applicant has canceled claims 11, 15, 19, 24, 28, 32 and 38-40 and added new claims 43-60, alleviating this rejection. In addition, Applicant has now amended claims 12 and 25 to include --contains one or more mutant genes or transgenes which have been introgressed therein, said mutant genes or transgenes selected from the group consisting of: a plant disease resistance gene, an insect resistance gene, a herbicide resistance gene, and a male sterility gene--, thereby limiting the claims to the types of mutant genes or transgenes that may be introduced and that are supported by the specification on pages 34-41, as suggested by the Examiner.

In addition, Applicant has canceled claims 34 and 40, thereby alleviating this rejection. Applicant respectfully asserts the following regarding double haploid breeding. The specification discusses multiple breeding techniques that may be used according to the invention. The specification at page 3 states "[p]lant breeding techniques known in the art and used and in a maize plant breeding program include, but are not limited to, recurrent selection backcrossing, pedigree breeding, restriction length polymorphism enhanced selection, genetic marker enhanced selection and transformation" (page 3, specification). Double haploid breeding is a technique long known and used in the art of plant breeding. Applicant is attaching herewith Wan *et al.*, "Efficient Production of Doubled Haploid Plants Through Colchicine Treatment of Anther-Derived Maize Callus", *Theoretical and Applied Genetics*, 77:889-892, 1989. This demonstrates ✓ that haploid breeding is a long known technique in the art of plant breeding and supports Applicant's assertion that producing double haploids is well known to one ordinarily skilled in the art. It is axiomatic in patent law that a specification "need not teach, and preferably omits, what is well known in the art." See *Spectra-Physics, Inc. v. Coherent, Inc.*, 3 U.S.P.Q.2d 1737, 1743 (Fed. Cir. 1987). Double haploids are produced by the doubling of a set of chromosomes (1N) from a heterozygous plant to produce a completely homozygous individual. This is advantageous because the process can eliminate the generations of selfing needed to obtain a homozygous plant from a heterozygous source. Applicant therefore respectfully requests withdrawal of the above rejections.

Claim 33 stands rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is more nearly connected, to make and/or use the invention. The Examiner states the claim is drawn towards a method of making a hybrid plant designated 32H58 comprising crossing inbred maize plants GE535764 and GE500871, however the Examiner states the terms of this deposit are not known.

Applicant respectfully traverses this rejection. Applicant herein submits the Deposits section has been amended in order to properly include both the hybrid maize plant 32H58 and the inbred parents GE535764 and GE500871 within the Deposit paragraph on page 42. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally filed specification. The specification has now been amended to correct these minor changes. Applicant thanks the Examiner for pointing out this inadvertent mistake.

In addition Applicant submits that the actual ATCC deposit will be delayed until receipt of notice that the application is otherwise in condition for allowance. As provided in 37 C.F.R. §§ 1.801-1.809, Applicant wishes to reiterate they will refrain from deposit of hybrid 32H58 and inbred parents GE535764 and GE500871 until allowable subject matter is indicated. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, description of the deposited biological materials sufficient to specifically identify and to permit examination and the name and address of the depository. The claims will also be amended to recite the proper ATCC deposit numbers. The Applicant provides assurance that:

- a) during the pendency of this application access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit will be maintained in a public depository for a period of thirty years, or five years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit will be conducted (see 37 C.F.R. § 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Therefore, Applicant submits at least 2500 seeds of hybrid maize plant 32H58 and the inbred parents GE535764 and GE500871 will be deposited with the ATCC. In view of this assurance,

the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02) Such action is respectfully requested.

Claims 8-19, 21-32 and 34-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office Action for claims 8-19 and 21-32. The Examiner stated that claims 12, 15, 25, 28 and dependents thereon are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plant. The Examiner further stated that claims 8, 16, 19, 21, 29, 32 and dependents thereon are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants.

Applicant respectfully traverses this rejection. The Examiner states the "the introgression of a gene of interest would in fact result in the introduction of additional, uncharacterized genetic material." Applicant points out that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. As stated in Poehlman *et al.* (1995) on page 334, submitted in the Information Disclosure Statement, a backcross derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Applicants further point out that cytoplasmic male sterility genes do not introduce linked nuclear genes. Wych (1988) on page 585-586, submitted in the Information Disclosure Statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile inbred to be the same variety as the F1 hybrid produced with the fertile version of the inbred. Applicants also refer the Examiner to Openshaw *et al.* submitted herewith, which states the "the backcross breeding procedure is being used widely to transfer simply inherited traits into elite genotypes...Today, backcrossing is being

used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm."

Nonetheless, in an effort to expedite prosecution, Applicant has canceled claims 9-11, 13-19, 22-24, 26-32, and 34-40 and amended claims 12 and 25 to include --contains one or more mutant genes or transgenes which have been introgressed therein, said mutant genes or transgenes selected from the group consisting of: a plant disease resistance gene, an insect resistance gene, a herbicide resistance gene, and a male sterility gene--. In addition, Applicant has added new claims 43-60 which specifically claim the introduction of a particular trait therein producing a maize plant with such desired trait thereby limiting the claims to the types of transgenes that may be introduced and that are supported by the specification as aforementioned. Applicant respectfully submits the claims come within the purview of the written description requirement and request reconsideration.

Claims 8, 12-19, 21, 25-32 and 34-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons stated in the last Office Action for 8, 12-19, 21 and 25-32.

Applicant respectfully traverses this rejection. Applicant herein submits the Deposits section has been amended in order to properly include both the hybrid maize plant 32H58 and the inbred parents GE535764 and GE500871 within the Deposit paragraph on page 42. The changes do not add new matter as there is literal support for the minor changes on page 7 in the originally filed specification. The Specification has now been amended to correct these minor changes. The Applicant further provides assurance that at least 2500 seeds of hybrid maize plant 32H58 and the inbred parents GE535764 and GE500871 have been deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02).

In addition, Applicant submits a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601. One of ordinary skill in the art of plant breeding would know how to evaluate the traits of two plant varieties to determine if there is no statistically significant variation when determined, for example, at a 5% significance level and

when grown in the same environmental conditions between the traits expressed by those varieties. Applicant claims progeny produced by backcrossing with 32H58 and retaining phenotypic characteristics of 32H58. Distinguishing identifying characteristics in the chemical and biotechnological arts, dealing with DNA, are those such as: partial structure, physical and/chemical properties, functional characteristics, known or disclosed correlation between structure and function, method of making, and combinations of the above. In plants, phenotypic characteristics are identifying characteristic correlated with DNA structure. It is respectfully submitted that Applicants' claims are sufficiently enabled and described by the specification.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 8-19 and 21-40 under 35 U.S.C. § 112, first paragraph.

Summary

Applicant acknowledges that claims 1-7, 20, and 41 are allowed.

Applicant further acknowledges that claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 are deemed free of the prior art. The Examiner further states the prior art fails to teach or fairly suggest plants which derive 50% or more of their alleles from the exemplified hybrid. This clearly indicates that hybrid maize plant 32H58 as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness. Therefore, Applicant respectfully submits that the deposit of the representative seed of 32H58 and inbred parents GE535764 and GE500871 should satisfy the description requirement. In light of the above, Applicant respectfully submits that the rejections under 35 U.S.C. § 112, first paragraph as improper and requests reconsideration and withdrawal of these rejections.

Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested.

This is a request under the provision of 37 CFR § 1.136(a) to extend the period for filing a response in the above-identified application for one month from June 3, 2003 to July 3, 2003.

Applicant is a large entity; therefore, please charge Deposit Account number 26-0084 in the amount of \$110.00 for one month to cover the cost of the extension.

Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lila Akrad". The signature is fluid and cursive, with a large loop at the beginning and a trailing end.

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